K072640

510(k) Summary

Summary Date:

DEC 2 1 2007

25 October, 2007

Applicant:

Iris Diagnostics, a Division of IRIS International Inc
9172 Eton Avenue
Chatsworth, CA 91311
(818) 709-1244
Gerald J. Haddock, P.E. RAC, Director, Quality Assurance and Regulatory Affairs

Proprietary and Established Names:

Proprietary name: IRISpec™ CA/CB/CC

Classification name: Quality control material (assayed and unassayed).

Common name: Urinalysis controls

Device to which substantial equivalence is claimed

IRISpec Urine Chemistry Control Part A and B.
Iris Diagnostics, a Division of IRIS International, Inc.
Chatsworth, CA 91311

File No. K945913

Description of the proposed device:

The proposed IRISpec™ CA/CB/CC Control is identical in its parts A and B to the unmodified IRISpec Urine Chemistry Control part A and Part B control currently in commercial distribution (K945913). The only difference between the predicate device and the proposed CA/CB/CC Urinalysis Control is that the new product has a claim for ascorbic acid in part C and the predicate device does not have a claim for ascorbic acid nor a part C. The matrix for part C is identical to that of part B so that part B is the negative control for ascorbic acid.

Intended Use:

IRISpec™ CA/CB/CC is an assayed QC material for monitoring of urine chemistry analytes and devices as listed on the package insert.

Comparison of the proposed device with the predicate device

Device	IRISpec™ CA/CB/CC (Proposed Device)	IRISpec Urine Chemistry Control, parts A and B (Predicate Device)
Similarities		
Composition	CA and CB are identical to parts A and B of predicate device. Matrix for CC is identical to that of CB	Synthetic matrix simulating human urine, with preservatives and bovine-sourced biological material for serum albumin, hemoglobin, and bilirubin . No human sourced materials.
Form	Same as predicate	Liquid, ready to use
Packaging-container	Same as predicate	Glass bottle with plastic screw cap
Packaging-fill volume	Same as predicate	100 mL
Preservatives	Same as predicate	0.0048% gluteraldehyde
Storage	Same as predicate	2° to 8° C Until expiration date
Stability-closed vial	Same as predicate	6 months at 2° to 8° C
Stability-open vial	Same as predicate	15 days at 2° to 8° C
Differences		
Intended use	IRISpec™ CA/CB/CC is an assayed QC material for monitoring of urine chemistry analytes and devices as listed on the package insert.	The IRISpec Urine Chemistry Controls are intended to be used as a quality control material for all CHEMSTRIP™ urine reagent strips
Analytes	Same as predicate device except for addition of ascorbic acid in CC	Specific Gravity, pH, Protein, Glucose, Ketones, Bilirubin, Blood, Nitrite, Urobilinogen, Leukocytes

Device Description

IRISpec™ CA/CB/CC controls are based on a synthetic matrix simulating human urine, with preservatives and bovine-sourced biological material for serum albumin, hemoglobin, bilirubin. No human sourced materials.

The following reagents are used in new CC:

L-Ascorbic Acid

Physical properties

Property	Value	Rationale for selection
Ascorbic Acid concentration	40 mg/dL (min)	Chosen so as to strongly saturate ascorbic acid pads on iChem 10 SG and vChem strips .
pH	5.0 (ref)	Same as CB control
Specific gravity	1.035 (ref)	Same as CB control
Base matrix	Identical to CB buffer	Chosen so that CB could be the negative for CC for ascorbic acid

Matrix Effects

Comparison testing was performed on three lots of the proposed CC control compared to human negative urine spiked with ascorbic acid at 40 mg/dL. Testing was performed in triplicate on the iChem 100 Urine Chemistry Analyzer. No measurement differences were observed.

Stability

Closed vial

Closed vial stability of proposed CC controls was verified in real time on samples from three lots stored at 2-8°C, compared to reference samples stored at -20°C. The semi-quantitative variable used as a measure of stability was concentration as measured by an iChem 100 Urine Chemistry Analyzer and iChem 10SG urine chemistry strips. The criterion for meeting the stability claim was no more than one grade change in concentration over a six month period

Samples were tested at the following time points: 1 month, 2 months, 3 months, 4 months, 6 months, and 7 months. These vials were compared to vials that were stored at -20C.

All vials tested had recoveries of 40mg/dL ascorbic acid for all three lots of IRISpec™CC controls after 7 months of real time stability. This study is ongoing for internal studies only since this surpasses the 6 month shelf life claim.

All negative controls (IRISpec™CA and IRISpec™ CB) tested NEG for ascorbic acid after 7 months of real time stability. This study is ongoing. However, this also passes the 6 month shelf life claim.

Accelerated Temperature Stability Studies

Triplicate samples of all three lots of the IRISpec™CC controls were stored at accelerated temperatures of 25° C for 20 days, 16 days, 10 days and 3 days. Triplicate samples of all three lots of IRISpec™CC controls were stored at accelerated temperatures of 35° C for 7 days, 6 days, 3 days, and 1 day. These were then compared to the triplicate samples of all three lots that were stored at 2-8° C (reference samples). All samples provided ascorbic acid values of 40 mg/dL during the entire length of the study at each temperature

Additionally, triplicate samples for all three IRISpec™ CC lots and IRISpec™ CA and IRISpec ™CB were incubated at 25° C for 6 months. These were also tested and compared to IRISpec™CC lots that were stored at 2-8° C. All IRISpec™ CC samples provided ascorbic acid values of 40mg/dL. All IRISpec™CA and CB controls were NEG for ascorbic acid, as expected.

"Surrogate" QC Material

"Surrogate" QC material effects are not applicable in the case of the part C control, because the QC material in the control is identical to the analyte it is intended to monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 1 2007

Iris Diagnostics,
a Division of IRIS International Inc
c/o Mr. Gerald J. Haddock
P.E. RAC, Director,
Quality Assurance and Regulatory Affairs
9172 Eton Avenue
Chatsworth, CA 91311

Re: K072640
Trade Name: IRISpec™ CA/CB/CC
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Code: JJW
Dated: October 20, 2007
Received: October 22, 2007

Dear Mr. Haddock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 809); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072640

Device Name: IRISpec™ CA/CB/CC

Indication For Use: IRISpec™ CA/CB/CC is an assayed QC material for monitoring of urine chemistry analytes and devices as listed on the package insert. For *in vitro* diagnostic (IVD) use only.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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